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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/826,055	04/03/2001	Douglas T. Gjerde	P-457	2447

7590

07/24/2003

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EXAMINER

SIEW, JEFFREY

ART UNIT

PAPER NUMBER

1637

DATE MAILED: 07/24/2003

18

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/826,055

Applicant(s)

GJERDE ET AL.

Examiner

Jeffrey Siew

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 June 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 34-73 is/are pending in the application.
- 4a) Of the above claim(s) 34-47, 52-65 and 68-73 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 48, 51, 66, 67 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 April 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election with traverse of Group II in Paper No. 17 is acknowledged. The traversal is on the ground(s) that both groups feature the same technical feature as they are both involve the enhancement of detection. This is not found persuasive because Group I clearly differs from Group II in that the dye must bind covalently whereas Group II involves a reversible DNA binding dye. The chemical reactants and bonds in each type of reaction are different. Moreover, the response argues that no undue burden of search would be required. As the nature chemical reactions are different, the search would require different chemical arts.

The requirement is still deemed proper and is therefore made FINAL.

Claims 34-47,52-65,68-73 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No.17.

The pending claims to be examined are claims 48-51,66 & 67.

### *Claim Rejections - 35 USC § 103*

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 48-50, 66 & 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oefner et al (Analytical Biochemistry vol. 223 pp. 001-008 1994) in view of Glazer et al (US5,763,162 June 9, 1998).

Oefner et al teach method of detection of polynucleotide separation by reverse phase ion pairing chromatography by contacting polynucleotide with dye (see whole doc. esp. abstract), apply to separation medium having nonpolar surface which is substantially free of multivalent cations (see abstract and page 2 reagents teaching the use of HPLC grade acetonitrile and nonporous polystyrene divinylbenzene particles), eluting complex with mobile phase containing counterion agent and organic solvent and detecting (see page 3 teaching the use of tetraalkylammonium salts).

Oefner et al do not teach reversible DNA binding dyes such as ethidium.

Glazer et al teach the use of reversible intercalating dyes such as ethidium dimer in detecting DNA in separation methods including HPLC. (see whole doc. esp. Abstract, col. 6 lines 24 & 25).

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One of ordinary skill in the art would have been motivated to apply Glazer et al's intercalating dyes to Oefner et al's separation technique in order increase the level of fluorescent efficiency. Glazer et al states that as opposed to covalently binding of dyes, intercalating dyes minimize self quenching and provide for high fluorescence efficiency (see col. 1 lines 65-67). It would have been prima facie obvious to apply Glazer et al's intercalating dyes to Oefner et al's reverse phase chromatography method in order to increase the fluorescent emission for detection.

3. Claim 51 is rejected under 35 U.S.C. 103(a) as being unpatentable over Oefner et al (Analytical Biochemistry vol. 223 pp. 001-008 1994) in view of Glazer et al (US5,763,162 June 9, 1998) in further view of Haugland (Handbook of Fluorescent Probes and Research Chemicals pages 221-229 1994).

The teachings and suggestions of Oefner et al and Glazer et al are described previously.

Oefner do not teach acridine orange or ethidium bromide.

Haugland teach acridine orange and ethidium bromide(see page 221 & 223).

One of ordinary skill in the art would have been motivated to apply Haugland's acridine orange or ethidium bromide to the combined detection method of Oefner et al and Glazer et al in order measure both double stranded DNA and RNA for diagnosis. Haugland states that the dyes offer very versatile and popular stains for detecting nucleic acids. It would have been prima facie obvious to apply the acridine orange or ethidium bromide to the DNA in Oefner et al's and Glazer et al's chromatographic method because the dyes were well known to provide successful and specific excitation maxima for the efficient detection of DNA.

### SUMMARY

4. No claims allowed.

### CONCLUSION

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Siew whose telephone number is (703) 305-3886 and whose e-mail address is Jeffrey.Siew@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner is on flex-time schedule and can best be reached on weekdays from 6:30 a.m. to 3 p.m. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703)-308-1119.

Any inquiry of a general nature, matching or filed papers or relating to the status of this application or proceeding should be directed to the Tracey Johnson for Art Unit 1637 whose telephone number is (703)-305-2982.


Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official

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Gazette, 1096 OG 30 (November 15, 1989). The CM1 Center numbers for Group 1600 are Voice (703) 308-3290 and FAX (703)-308-4242.

  
**JEFFREY NEW**  
**PRIMARY EXAMINER**

July 23, 2003